

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/003,669	BROYLES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Q. JANICE LI, M.D.	1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/19/08.
2. ☒ The allowed claim(s) is/are 29,30 and 38-40.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
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/Q. JANICE LI, M.D./  
Primary Examiner, Art Unit 1633

***NOTICE OF ALLOWANCE***

The amendment filed September 19, 2008 is acknowledged. Claims 1-28, 31-37 have been cancelled. Claim 29 has been amended. Claims 39 and 40 are newly submitted. Claims 29, 30, 38-40 are pending and under current examination.

All of the amendments have been thoroughly reviewed and entered. Upon further search and consideration, the previous rejections in the Office action mailed on 5/16/08 are withdrawn in view of the amendments.

***EXAMINER'S AMENDMENT***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Barbara Krebs Yuill on December 3, 2008.

The specification has been amended as follows:

In page 28 of the specification, the phrase --(SEQ ID Nos: 3-7)-- was inserted after the word "sequences" in line 21.

In page 29 of the specification, the phrase --(SEQ ID Nos: 8-19)-- was inserted after the word "promoters" in line 18.

The following is an examiner's statement of reasons for allowance:

Claims are drawn to a method for repressing production of beta-globin proteins and increasing production of gamma-globin proteins via over-expressing ferritin-H subunit. The cited art of record *Picard et al.* suggests that over-expression of ferritin-H suppresses  $\beta$ -globin gene. However, as indicated by the applicant, the mouse cells tested in *Picard et al.* do not produce gamma-globin proteins, and the prior art of record fails to teach the effect of ferritin-H on gamma-globin production.

As to the inter-relationship between  $\gamma$ - and  $\beta$ -globin, *Lloyd et al.* (Mole Cell Biol 1992;12:1561-7) teaches the presence of the  $\gamma$ -globin gene is sufficient to down-regulate the  $\beta$ -globin gene in embryonic transgenic mice comprising an LCR-  $\gamma$ - $\beta$ -globin mini construct, but  $\gamma$ -globin gene can be down-regulated automatically *independent* of  $\beta$ -globin gene (e.g. the abstract). Accordingly, the prior art of the record fails to teach or predictably expect that ferritin-H is capable of repressing beta-globin gene as well as increasing gamma-globin production. Accordingly, the prior art of the record does not teach or suggest the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Claims 29, 30, 38-40 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on 571-272-0739. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

*/Q. JANICE LI, M.D./*  
*Primary Examiner, Art Unit 1633*

Q. Janice Li, M.D.  
Primary Examiner  
Art Unit 1633

*QL*

December 5, 2008